



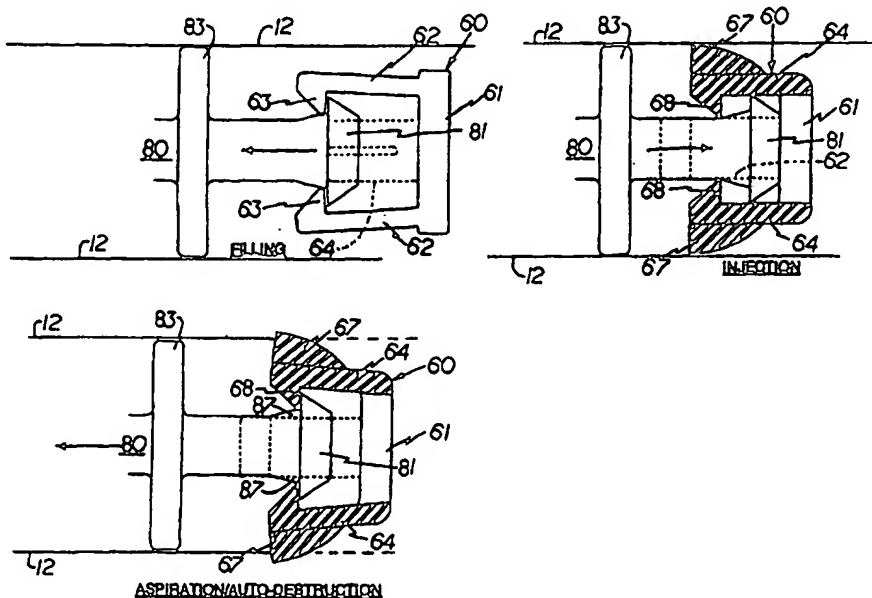
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶: A61M 5/50	A1	(11) International Publication Number: WO 97/26933 (43) International Publication Date: 31 July 1997 (31.07.97)
(21) International Application Number: PCT/CA97/00066 (22) International Filing Date: 24 January 1997 (24.01.97) (30) Priority Data: 2,168,201 26 January 1996 (26.01.96) CA (71)(72) Applicant and Inventor: CAMPBELL, Douglas, C., V. [CA/CA]; Suite 202-203, 190 Colonade Road, Ottawa, Ontario K2E 7J5 (CA). (72) Inventors; and (75) Inventors/Applicants (for US only): FRISE, Peter [CA/CA]; 16 Bluegrass Drive, Kanata, Ontario K2M 1G4 (CA). JOHNSON, Frank [CA/CA]; 169 Fifth Avenue, Ottawa, Ontario K1S 2M8 (CA). (74) Agents: FRITZ, Joachim, T. et al.; Scott & Aylen, 1000-60 Queen Street, Ottawa, Ontario K1P 5Y7 (CA).		(81) Designated States: AL, AM, AT, AU, AZ, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, US, UZ, VN, ARIPO patent (KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the</i> <i>claims and to be republished in the event of the receipt of</i> <i>amendments.</i>

(54) Title: AUTO-DESTRUCT DISPOSABLE SYRINGE**(57) Abstract**

A disposable auto-destruct syringe is disclosed which includes a syringe barrel for holding an injectable fluid, a piston reciprocable in the barrel and sealingly engaging the barrel wall, a plunger having a forward portion normally positioned in the barrel and a rearward portion to be manipulated by a user of the syringe, a coupling mechanism for connecting the piston with the plunger to permit axial movement of the piston in the barrel by operation of the plunger, and a deforming structure for permanently deforming the barrel wall to break the seal between the piston and the barrel wall. The deforming structure is in the form of cutters or burrowing

elements mounted by way of elastic arms to one of the piston and the plunger. The deforming structure is movable from an at rest position wherein the barrel wall is not deformed, to a barrel wall engaging position wherein the barrel wall is permanently deformed by the deforming structure. The syringe further includes an engaging mechanism for forcing the deforming structure into the barrel wall engaging position upon rearward movement of the piston after a full or partial injection stroke only. The engaging mechanism is mounted to the other of the piston and plunger. This construction provides for an auto-destruct syringe wherein the barrel wall is permanently deformed not during the injection stroke, but only when refilling of the syringe is attempted after a full or partial injection stroke so that the auto-destruction action does no longer interfere with the injection stroke.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AM	Armenia	GB	United Kingdom	MW	Malawi
AT	Austria	GE	Georgia	MX	Mexico
AU	Australia	GN	Guinea	NE	Niger
BB	Barbados	GR	Greece	NL	Netherlands
BE	Belgium	HU	Hungary	NO	Norway
BF	Burkina Faso	IE	Ireland	NZ	New Zealand
BG	Bulgaria	IT	Italy	PL	Poland
BJ	Benin	JP	Japan	PT	Portugal
BR	Brazil	KE	Kenya	RO	Romania
BY	Belarus	KG	Kyrgyzstan	RU	Russian Federation
CA	Canada	KP	Democratic People's Republic of Korea	SD	Sudan
CF	Central African Republic	KR	Republic of Korea	SE	Sweden
CG	Congo	KZ	Kazakhstan	SG	Singapore
CH	Switzerland	LI	Liechtenstein	SI	Slovenia
CI	Côte d'Ivoire	LK	Sri Lanka	SK	Slovakia
CM	Cameroon	LR	Liberia	SN	Senegal
CN	China	LT	Lithuania	SZ	Swaziland
CS	Czechoslovakia	LU	Luxembourg	TD	Chad
CZ	Czech Republic	LV	Latvia	TG	Togo
DE	Germany	MC	Monaco	TJ	Tajikistan
DK	Denmark	MD	Republic of Moldova	TT	Trinidad and Tobago
EE	Estonia	MG	Madagascar	UA	Ukraine
ES	Spain	ML	Mali	UG	Uganda
FI	Finland	MN	Mongolia	US	United States of America
FR	France	MR	Mauritania	UZ	Uzbekistan
GA	Gabon			VN	Viet Nam

AUTO-DESTRUCT DISPOSABLE SYRINGE

Field of the Invention

The invention relates to disposable syringes and especially syringes of the auto-destruct type which are rendered non-reusable during or after a first use.

5 Background of the Invention

Communicable diseases are transmitted in different ways, for example, by contact with body fluids of an infected person. Infection with a communicable disease is undesired and is especially unfortunate when due to inadvertance or ignorance such as when caused by the sharing or reuse of hypodermic syringes. The practise of sharing and/or
10 reusing hypodermic syringes is especially prevelant among drug users and in third world countries where syringes are used in vaccination campaigns. Often several children are inoculated with the same syringe either by using large capacity syringes for multiple small injections, or by refilling and reusing the syringes after insufficient sterilization. As a result potentially disasterous, body fluid transmitted diseases,
15 especially AIDS and Hepatitis have spread at an alarming rate among drug users and in third world countries, and there particularly among children. Although not all new cases are attributable to syringe reuse or sharing, it is estimated by the World Health Organization that the total number of new cases could be significantly reduced if transmission through contaminated syringes were prevented. In an effort to frustrate the
20 reuse of hypodermic syringes, disposable syringes have been developed which are intended to operate only for one single injection.

Various single-use syringe constructions are known in the art, which can be grouped into three basic categories; the piston or plunger lock type, wherein retraction of the
25 piston is prevented either always or after completion of the injection; the plunger separating type, wherein the plunger separates from the piston or the piston seal when the plunger is retracted; and the cutting type wherein the barrel wall is cut during injection. It is a major disadvantage that in the first two types of single-use syringes the barrel which is the most important part of any functioning syringe remains intact
30 and may be tampered with and reused. Thus, single-use syringes wherein the barrel is

rendered unusable, for example through cutting of the barrel wall, are preferable. However, the cutting type syringes also have certain disadvantages.

5 Chiquar-Arias in U.S. Patent No. 3,667,657 disclose prefilled syringes which include a small stationary knife that is laterally fixed to the syringe plunger and engages an opening in the wall of the syringe barrel. When the plunger is forced down into the barrel, as during injection, the barrel wall is cut. This destroys the barrel behind the piston seal and makes reuse of the syringe impossible. However, it is a disadvantage of prefilled syringes that they can only be used in those circumstances where injection
10 of the respectively included liquid is desired. In other words, numerous syringes filled with different inoculants are required which increases manufacturing and storage costs.

15 In U.S. Patent No. 3,951,146 Chiquar-Arias describe syringes wherein the plunger includes a housing or recess for a small knife which is forced radially outwardly by a spring. The knife has a rounded rear edge and a forward cutting edge. The plunger can be moved backward for fillig of the syringe without cutting or damaging the barrel wall. For insertion of the plunger, a protection strip is inserted between the knife and the barrel wall, which strip is then removed. Use of the protection strip is
20 disadvantageous, since it adds an additional manufacturing step and, thus, increases production cost. Furthermore, the spring loaded knife stays in contact with the barrel wall at all times, which, despite the rounded rear edge of the knife, could damage the barrel wall during aspiration of the inoculant and lead to leakage around the plunger or through the barrel wall.

25 An auto-destruct disposable syringe with retractable knives is disclosed in Canadian Patent Application SN. 2,045,499 by Fenet. The syringe includes a barrel, a piston, and a plunger for moving the piston axially in the plunger. The knives are mounted on flexible arms which are connected with the plunger and are retracted during the
30 aspiration stroke of the syringe. When the aspirated liquid is expelled from the barrel during injection, the plunger is pushed against the piston which moves the free end of

the arms along a ramp on the piston. This forces the knives against the barrel wall. The plunger and, thus, the knives are oriented to be opposite preselected areas of reduced thickness in the barrel wall. The reduced wall thickness permits penetration of the knives and cutting of the barrel wall, thereby destroying the barrel behind the piston as it is forced into the barrel during injection. As a result, the syringe cannot be reused, since the barrel will no longer hold a vacuum and any liquid contained therein will leak through the cut areas of the barrel wall.

It is a disadvantage of this syringe construction that the auto-destruct mechanism thereof can be rendered useless by rotating the plunger in the barrel until the knives can no longer engage the weakened areas in the barrel wall during injection. Furthermore, if the barrel wall in the weakened areas is too thin, barrel integrity may be compromised resulting in a bursting of the barrel during injection. On the other hand, if the wall thickness in the weakened areas is too large, the cumulative force required for moving the piston down the barrel and simultaneously cutting the barrel wall during injection may become excessively large. This may render the syringe impractical. It also may result in rejection of the syringe under national and/or international regulations which, for example, require that a maximum axial force required for pushing the piston down the barrel during injection not be exceeded. Moreover, since auto-destruct syringes must be discarded after a single use, they should be made available at the lowest possible price to reduce the financial strain on the patient, the health care system and international health organizations. This requires that the syringe be manufactured from relatively economical materials such as plastics. However, during tests with knives manufactured from plastics material, the inventors of the present application have found that knives made from inexpensive plastics tend to quickly become blunt. This may lead to failure of the knives part way during the injection stroke leaving the front portion of the barrel intact and allowing partial reuse of the syringe. Thus, an economical auto-destruct syringe is desired which reliably prevents even partial reuse.

Summary Of The Invention

These disadvantages are now overcome with an auto-destruct syringe in accordance with the invention wherein the integrity of the syringe is reliably destroyed not during the injection stroke but only when refilling of the syringe is attempted, i.e. during a second aspiration stroke. Preferably, this is achieved by cutting of the syringe barrel starting at the front end or by braking the seal between the barrel wall and the piston, for example by permanently deforming the barrel wall. Thus, the axial forces required for permanently deforming the syringe barrel, for example by cutting, are no longer superimposed onto the basic force required for pushing the piston down the barrel during injection. In other words, the self-destruction operation of the syringe can no longer interfere with the injection stroke. Furthermore, should the elements used for deformation of the barrel wall fail after part of the second aspiration stroke, destruction of the syringe is nevertheless reliably achieved, since deformation of the barrel wall commences at the front end of the barrel.

In a preferred embodiment, the thickness of the syringe barrel wall is significantly reduced compared to conventional auto-destruct syringes and along the whole circumference of the barrel. The wall thickness is selected to permit permanent deformation of the barrel wall with cutting or burrowing elements mounted to the syringe plunger or piston thereby breaking the seal between the barrel wall and the piston. Since the barrel wall is evenly thin about the whole circumference of the barrel, deformation of the barrel wall is possible in any rotational orientation of the plunger or piston.

In another preferred embodiment, permanent deformation of the barrel wall is achieved with blunt burrowing elements mounted to the piston which are forced radially outward against the barrel wall during the second aspiration stroke and generate a permanent groove in the inner surface of the barrel wall which cannot be sealed by the piston or a piston seal mounted thereon so that air can pass around the piston. Thus, the seal between the piston and the barrel wall is broken during the second aspiration stroke

and ahead of the rearward moving piston, so that the syringe will no longer hold a vacuum and cannot be refilled.

Accordingly, the invention provides an auto-destruct syringe comprising

5 a syringe barrel for holding a fluid having an open rear end and a closed front end and a passage extending through the closed front end to permit expulsion of fluid from the interior of the barrel;

a piston reciprocable in the barrel and sealingly engaging the barrel wall;
10 a plunger having a forward portion normally positioned in the barrel and a rearward portion to be manipulated by a user of the syringe;

coupling means for connecting the piston with the plunger to permit axial movement of the piston in the barrel by operation of the plunger;

deforming means for permanently deforming the barrel wall to brake the seal between the piston and the barrel wall, the deforming means being mounted to
15 one of the piston and the plunger and movable from an at rest position wherein the barrel wall is not deformed by the deforming means, to a barrel wall engaging position wherein the barrel wall is permanently deformed by the deforming means; and

engaging means for forcing the deforming means into the barrel wall engaging position upon rearward movement of the piston after a full or partial injection
20 stroke, the engaging means being mounted to the other of the piston and plunger.

The term permanently deforming the barrel wall in the context of this application is intended to include puncturing or cutting of the barrel wall, burrowing into the side wall to produce a permanent groove, and other actions which will break the seal
25 between the piston and the barrel wall and allow leakage around the piston, thereby preventing the generation of pressure or vacuum in the barrel.

Brief Description Of The Drawings

Preferred embodiments of the invention will now be further described by way of
30 example only and with reference to the attached drawings, wherein

Fig. 1 is an axial cross-section of a preferred embodiment of the auto-destruct syringe in accordance with the invention;

Fig. 2 is an enlarged side view of the plunger of the embodiment shown in Fig. 1;

5 Fig. 2a is a cross-section through the plunger shown in Fig. 2 taken along line 2a-2a;

Fig. 3 is an axial cross-section taken along the plane of Figs. 1 and 2 through the piston/plunger combination of the preferred embodiment shown in Fig. 1 during the first aspiration stroke;

10 Fig. 4 is an axial cross-section through the piston/plunger combination shown in Fig. 3 but taken along a plane orthogonal to the plane of Fig. 3 and illustrating the combination during the injection stroke;

Fig. 5 illustrates the piston/plunger combination shown in Fig. 4 but during the second aspiration stroke;

15 Fig. 6 is an axial cross-section through the piston/stopper combination of the embodiment shown in Fig. 1;

Fig. 7 is a rear end view of the piston seal of the embodiment shown in Fig. 1;

20 Fig. 8 is a cross-section through the piston/stopper combination taken along a plane rotated 45° from the one of Fig. 6; and

Fig. 9 illustrates the piston/plunger combination shown in Fig. 5 but with deforming elements which have blunt edges and burrow into the barrel wall instead of cutting it.

Detailed Description Of The Preferred Embodiments

25 The preferred embodiment of an auto-destruct disposable syringe in accordance with the invention is packaged in the empty condition and allows aspiration of an injectable liquid prior to injection. The syringe includes a mechanism which breaks the seal between the piston of the syringe and the syringe barrel when reuse is attempted after full or partial injection.

30

In general, a syringe in accordance with the invention as shown in Fig. 1 of the drawings consists of a syringe body 10 including a barrel 12, a piston assembly 50 including a piston 60 and an auto-destruct mechanism for permanent deformation of the barrel wall 13, a plunger 80 and a coupling mechanism connecting the plunger 80 with the piston 50 thereby allowing the user of the syringe to reciprocate the piston by way of the plunger.

The syringe body 10 consists of the cylindrical barrel 12 which has an open rear end 14 and a closed front end 20. A collar 16 is provided at the rear end 14 which includes a pair of diametrically opposite wings 18 that provide finger rests during aspiration and injection. The front end 20 of the barrel is provided with an integral needle-mount 22 for attachment of a hypodermic needle 30. The front end 20 further has a fluid passage 23 for the expulsion of fluid from the barrel interior and into the needle 30. Although the needle 30 can be removably attached to the mount 22 for separate disposal, it is preferably permanently affixed to the needle mount 22 to prevent the reuse of possibly contaminated needles with new syringes.

The piston assembly 50 includes a substantially cup-shaped piston seal or stopper 52 which is made of elastomeric seal material such as butyl rubber used in conventional syringe piston seals. Although use of a piston seal in the form of a separate stopper is preferred, it is known in the art that a satisfactory seal between the piston and the barrel wall can be achieved without separate stoppers, i.e. by seals integrated into the piston or by tight engagement between the piston and the barrel wall. The stopper 52 is connected with piston 60 by way of an interference fit (see Figs. 6-8). The cylindrical sidewall 51 of the stopper 52 has an outer diameter which is slightly larger than the inner diameter D of the barrel 12 to ensure a liquid tight sliding engagement therebetween. A circumferential groove 53 is provided in the outer surface of the stopper sidewall 51 to improve the sealing characteristics of the stopper. In the alternative, the stopper can have a diameter which is marginally smaller than the barrel diameter D and include one or more circumferential sealing ribs giving the stopper an overall diameter larger than D thereby ensuring a reliable seal. At the piston engaging

end, the stopper sidewall 51 is provided with four circumferentially equally spaced, radially inwardly projecting flaps 55 which are integral with the sidewall 51 and extend between the drag/carrier arms of the piston that will be described in more detail in the following.

5

The piston 60 (see Figs. 3-5) has a cylindrical base 61 which snugly fits into the stopper 52 and two pairs of arms extending from the base in rearward direction. A pair of diametrically opposed axially extending drag arms 62 form a coupling mechanism for connecting the piston 60 with the plunger 80. To this end, each drag arm has a hook-shaped rear end 63 for engagement with an enlarged, mushroom shaped head 81 on the forward end 83 of the plunger 80. This provides a coupling mechanism which allows the piston 60 to be moved rearward in the barrel 12 by pulling back the plunger 80 during the initial aspiration stroke.

10

The plunger 80 (see Figs. 2 and 2a) has a shaft 82 of substantially square cross-section and guide plates 83 integral with the shaft 82 to center the shaft in the barrel. A thumb plate 84 is integrally molded onto a rear end 85 of the shaft, while the forward end 86 of the plunger, which end normally extends into the barrel 12, includes the mushroom-shaped head 81 for engagement by the hook-shaped ends 63 of the drag arms 62. The shaft front end is further provided with a frustoconical forwardly inclined ramp portion 87 which is located behind head 81 and forms part of a barrel wall deforming mechanism 90 of the syringe.

20

The barrel wall deforming mechanism 90 provides for permanent deformation of the barrel wall 12 when an attempt is made to refill the syringe. This breaks the seal between the stopper 52 and the barrel wall, which renders the syringe useless. The deforming mechanism consists of a pair of diametrically opposed axially extending flexible carrier arms 64 connected to and extending rearward from the piston base 61. The carrier arms 64 and the drag arms 62 are alternately positioned and circumferentially evenly spaced about the center of the piston base 61. The carrier arms 64 respectively include at their free end a radially outwardly protruding integral

25

30

deforming element 66 such as the sharp- edged cutters 67 of substantially triangular cross-section illustrated in Figs. 3-5, or a blunt edged burrowing element 67a (see Fig. 9) which is preferably of the same size and shape as the cutters 67, but has rounded edges and therefore burrows into the barrel wall instead of cutting it. A radially inwardly directed hook portion 68 is provided at the free end of each carrier arm 64 which hook portion provides for a reliable connection between the piston and the plunger during the second aspiration stroke (auto-destruction stroke) and, thus, prevents disconnection of the plunger from the piston subsequent to injection. In the normal, at rest position of the carrier arms, the deforming elements 66 are not forced against the barrel wall and are preferably closely spaced therefrom (see Fig. 3). However, the hook portions 68 protrude radially inwardly to such an extent that they engage the ramp portion 87 on the forward end 83 of the plunger 80 when the latter is completely inserted into the piston 60 (see Fig. 4). Furthermore, the hook portions 68 ride up on the ramp portion 87 when the plunger is pulled back in the piston 60 until the rear face of the plunger head 81 engages the hook portions, thereby forcing the attached deforming elements 66 into the barrel wall. The angle of the ramp portion 87 is selected such that the deforming elements are pushed radially outwardly with sufficient force to result in permanent deformation of the barrel wall and, thus, breaking of the seal between the stopper and the barrel wall. In the preferred embodiment the ramp portion 87 encloses an angle with the longitudinal axis of the plunger 80 of 15°-45° depending on the material, shape and type of the deforming element 66 respectively used and on the material and thickness of the barrel wall adjacent the deforming element. The cutting elements are preferably extrusion molded of the same material as the remainder of the piston 60, for example polypropylene. However, they can also be made of a tougher or harder material such as polycarbonate, especially when the deforming elements are intended to cut the barrel wall.

Although the above described coupling mechanism is preferred for use in a syringe in accordance with the invention, other coupling elements which provide a reliable connection between the plunger and the piston during the first and second aspiration strokes and permit sufficient movement therebetween for engagement of the deforming

mechanism. Furthermore, the coupling mechanism and the deforming mechanism can be combined into a single structure, for example, by mounting the hook portions 68 and the deforming elements 66 on the drag arms.

5 The drag arms 62 in the preferred embodiment are longer than the carrier arms 64. The hook-shaped ends 63 of the drag arms 62, the head 81 of the shaft, the ramp portion 87 and the hook portions 68 of the carrier arms 64 respectively are dimensioned such that when the plunger is inserted into the piston until the hook-shaped ends 63 engage behind the head 81, the hook portions 68 and ramp portion 87 are axially spaced apart. Furthermore, the drag arms 64 are shaped such that the hook-shaped ends 63 thereof are normally radially spaced apart from the barrel wall. The spacing is selected such that the drag arms 62 do not engage the barrel wall when the mushroom-shaped head 81 of the plunger 80 is positioned therebetween during assembly of the syringe. It will be apparent from the above description and the attached drawings that the stopper 52 extends rearward around the piston 60, or in other words the piston is recessed into the stopper in the preferred embodiment. As a result, the deforming elements 66 are located closely adjacent the seal line between the stopper 52 and the barrel wall 12 so that substantially no portion of the barrel wall will remain intact when refilling of the syringe is attempted after injection.

20 The piston 60 with the drag and carrier arms 62, 64 and the plunger 80 are each preferably integrally extrusion molded from an extrudable, thermoplastic material, preferably polypropylene.

25 Although in the above described arrangement of the coupling and deforming mechanisms is preferred, it will be readily apparent that the location of the drag arms 62 and the mushroom shaped head 81 on the piston 60 and plunger 80 respectively can be exchanged without having an effect on the function of the syringe of the invention. Equally, the positions of the carrier arms 64 with the deforming elements 66 and of the ramp portion 87 may be exchanged so that the carrier arms are affixed to the plunger 30 80 and the ramp portion is provided on the piston 60.

To facilitate permanent deformation of the barrel wall, the thickness of the barrel wall can be reduced along diametrically opposite grooves 106 as known in the art from the self-destruct syringe disclosed by Fenet in Canadian Patent Application SN 2,045,499. If the barrel wall is provided with such grooves, the rotational position of the carrier arms 64 in the barrel must be controlled to ensure reliable engagement of the deforming elements 66 with the grooves. Furthermore, it may be possible to render the syringe reusable by rotating the piston 60 in the barrel until the deforming elements 66 are no longer opposite one of the grooves. In order to prevent this, the barrel wall in the preferred embodiment is made evenly thin along its whole circumference so that rotation of the piston 66 in the barrel no longer has any effect on the function of the deforming elements. Furthermore, in the most preferred embodiment, the deforming elements 66 are burrowing elements 67 which have a blunt radially outer edge that does not cut the barrel wall but simply burrows into the barrel wall to create a permanent groove which permits air to pass around the plunger. Consequently, reuse of the syringe is made impossible, since the barrel will no longer hold the vacuum required for refilling of the syringe. Moreover, when the barrel wall is made evenly thin, permanent deformation of the barrel wall by the deforming elements may be carried out either during the injection or the second aspiration stroke. The barrel wall is preferably of a thickness of 0.01 to 0.2 mm and extrusion molded of a substantially rigid thermoplastic material to withstand the pressures created during aspiration and injection. The barrel wall is preferably extrusion molded from polypropylene, but other thermoplastic materials may be used as well.

The syringe is preferably assembled by pushing the piston completely into the barrel and inserting the plunger into the barrel. The plunger 80 is then forced against the piston 60 until the mushroom-shaped head 81 of the plunger snaps into the piston immediately behind the hook-shaped ends of the drag arms 62. A circumferential crimp 100 is then provided in the barrel wall 12. The location of the crimp is selected such that it limits the maximum volume of liquid which can be aspirated. Changing the location of the crimp 100 allows syringes of the same construction and dimensions being used for a range of standard injection volumes (0.1 ml - 0.5 ml). The crimp also

prevents disassembly of the syringe and tampering with the barrel wall deforming mechanism 90. Once fully assembled, the syringe is sterilized, packaged and shipped in the completely assembled but empty condition.

5 During use, the syringe is first filled or aspirated by pulling back the plunger 80 which creates a vacuum in the syringe and leads to filling of the barrel with aspirated fluid in a manner well known in the art. For injection, the plunger is forced into the barrel to advance the piston 60 and expell the fluid contained in the barrel. The forward force imparted on the thumb plate 84 during the injection stroke forces the head 81 of the
10 plunger deeper into the piston until the front surface 85 of the head engages the base 61 of the piston. At this point, the hook portions 68 have moved sufficiently past the peaks of the ramp portion 87 to prevent engagement of the deformation elements 66 with the barrel wall during injection. The deforming elements 66 are only temporarily forced into engagement with the barrel wall at the beginning of the injection stroke
15 when the hook portions 68 move past the ramp portion 87. Thus, at the end of the injection stroke, the integrity of the barrel is still in place. However, if the plunger is pulled back to attempt a second aspiration, the ramp 87 and the hook portions 68 are forced into mutual engagement and the deforming elements are forced into or through the sidewall and held in a sidewall deforming position as long as the plunger is pulled
20 back during this third stroke of the piston/plunger combination. This results in the barrel wall being permanently deformed and the syringe rendered completely unusable as soon as a second aspiration is attempted. The connection between the front end 83 of the plunger 80 and the cutter arms is sufficient to prevent disconnection of the plunger from the piston during the third stroke. Furthermore, the front end of the
25 plunger is preferably of sufficient strength to withstand the tension forces created during the third stroke so that the plunger front end does not break off during the cutting operation. However, in an alternate embodiment, the plunger shaft 82 may be provided with an area of reduced cross-section (not illustrated) behind the mushroom shaped head 81 so that the head will break off when excessive rearward force is applied
30 to the plunger 80. For situations where it is desired that the user of the syringe be able to remove a portion of the plunger before disposal of the syringe for exchange of that

portion for a new syringe, as in a needle exchange program, the plunger shaft 82 is provided with a region of reduced cross-section 109 behind the rearmost guide plate 83 of the plunger 80.

- 5 Changes and modifications in the specifically described embodiments can be carried out without departing from the scope of the invention which is intended to be limited only by the scope of the appended claims.

THE EMBODIMENTS OF THE INVENTION IN WHICH AN EXCLUSIVE
PROPERTY OR PRIVILEGE IS CLAIMED ARE DEFINED AS FOLLOWS

1. An auto-destruct syringe, comprising
5 a syringe barrel for holding a fluid having an open rear end and a closed front end and a passage extending through the closed end of the barrel to permit expulsion of fluid from the interior of the barrel;
a piston reciprocable in the barrel and sealingly engaging the barrel wall; a plunger having a forward portion normally positioned in the barrel and a
10 rearward portion to be manipulated by a user of the syringe;
coupling means for connecting the piston with the plunger to permit axial movement of the piston in the barrel by operation of the plunger;
deforming means for permanently deforming the barrel wall to brake the seal between the piston and the barrel wall, the deforming means being mounted to
15 one of the piston and the plunger and movable from an at rest position wherein the barrel wall is not deformed by the deforming means, to a barrel wall engaging position wherein the barrel wall is permanently deformed by the deforming means; and
engaging means for forcing the deforming means into the barrel wall
engaging position upon rearward movement of the piston after a full or partial injection
20 stroke, the engaging means being mounted to the other of the piston and plunger.
2. An auto-destruct syringe as defined in claim 1, wherein the barrel wall has a longitudinally extending region of reduced thickness in the area engaged by the
25 deforming means during rearward movement of the piston after a full or partial injection stroke.
3. An auto-destruct syringe as defined in claim 2, wherein the whole barrel wall is of reduced thickness and along the whole circumference thereof.
- 30 4. An auto-destruct syringe as defined in claim 1, further including stop means for preventing removal of the plunger from the barrel.

5. An auto-destruct syringe as defined in claim 4, wherein the stop means is a circumferential, radially inwardly extending crimp in the barrel wall.

6. An auto-destruct syringe comprising

5 a syringe barrel for holding a fluid, the barrel having an open rear end and a closed front end and a passage extending through the closed end of the barrel to permit expulsion of fluid from the interior of the barrel, the wall of the barrel being of a thickness of 0.01 to 0.2 mm and extruded of a substantially rigid thermoplastic material to withstand the pressures created during aspiration and injection;

10 a piston reciprocable in the barrel and sealingly engaging the barrel wall; a plunger having a forward portion normally positioned in the barrel and a rearward portion to be manipulated by a user of the syringe;

coupling means for connecting the piston with the plunger to permit axial movement of the piston in the barrel by operation of the plunger;

15 deforming means for permanently deforming the barrel wall to brake the seal between the piston and the barrel wall, the deforming means being mounted to one of the piston and the plunger and movable from an at rest position wherein the barrel wall is not deformed by the deforming means, to a barrel wall engaging position wherein the barrel wall is permanently deformed by the deforming means; and

20 engaging means for forcing the deforming means into the barrel wall engaging position upon one of forward movement of the piston during injection and rearward movement of the piston after a full or partial injection stroke, the engaging means being mounted to the other of the piston and plunger.

25

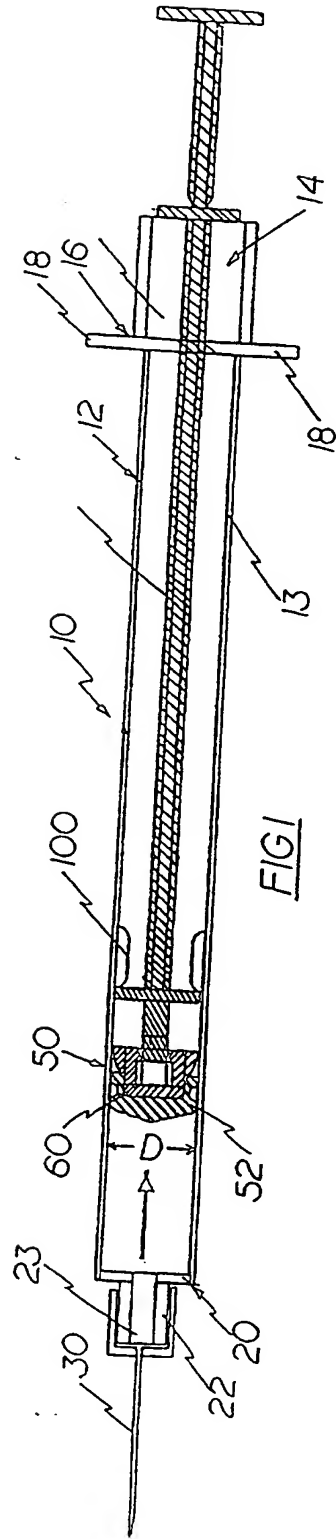


FIG 1

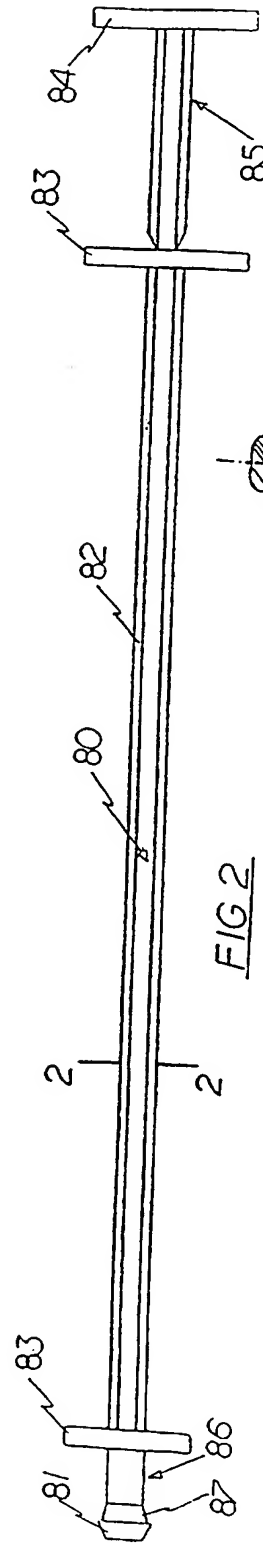


FIG 2

FIG 2a

SUBSTITUTE SHEET (RULE 26)

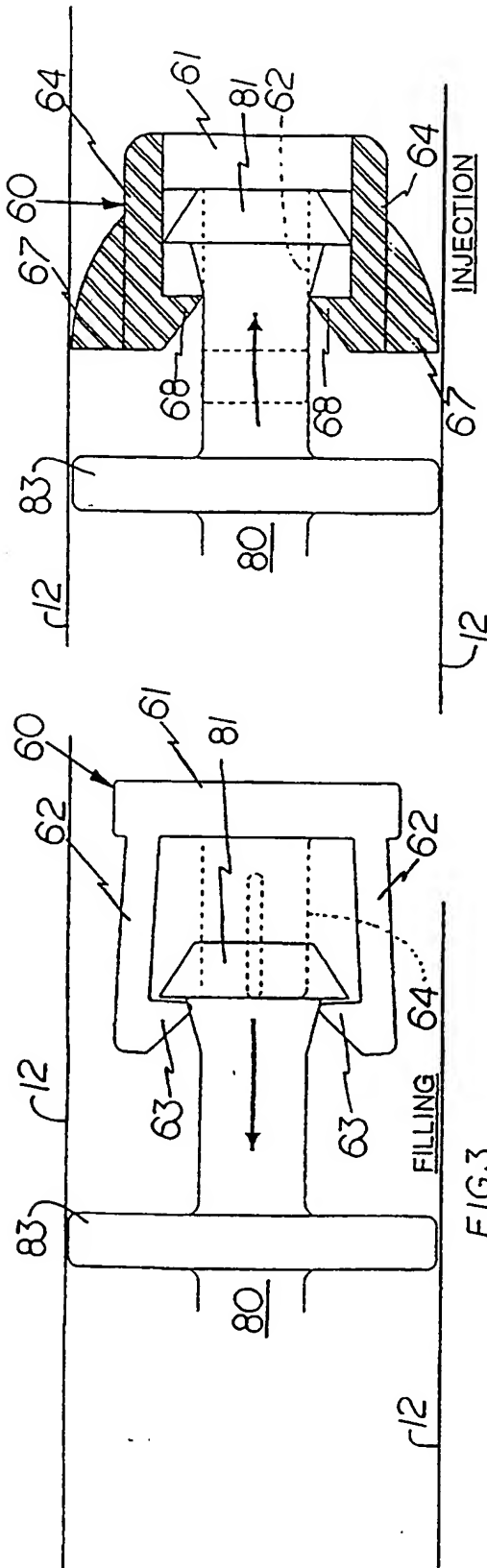
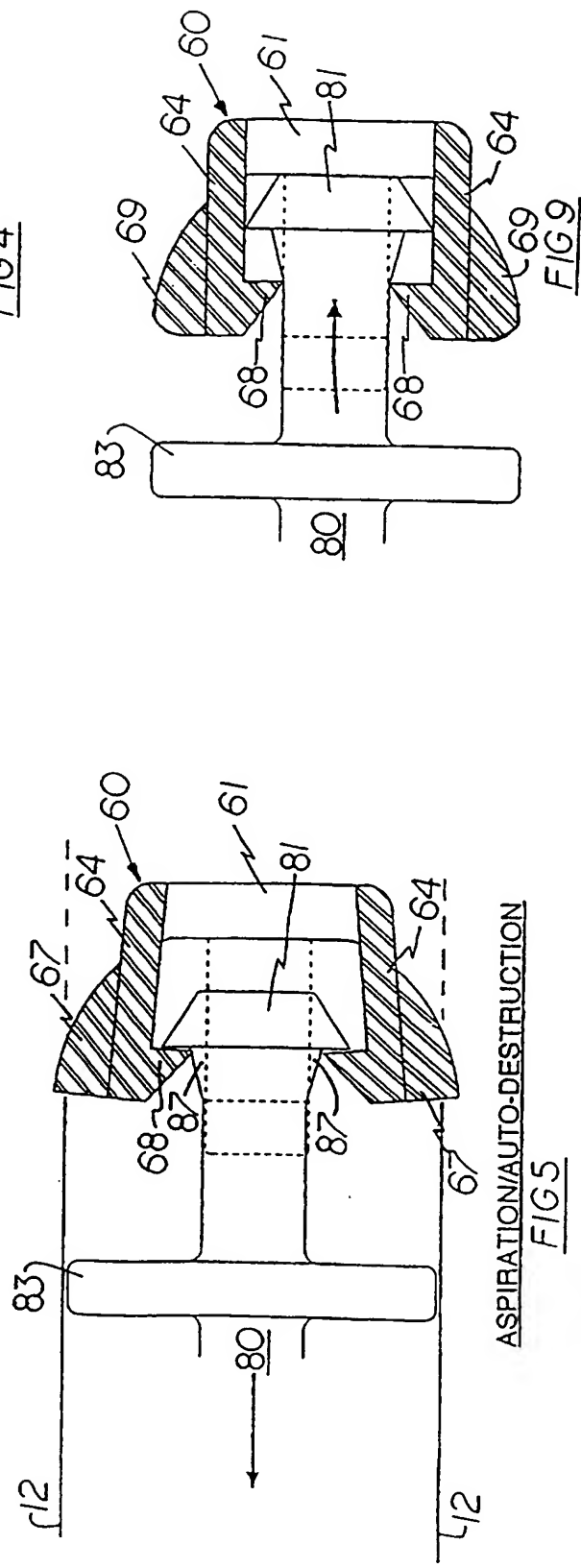


FIG 4



ASPIRATION/AUTO-DESTRUCTION

FIG 5

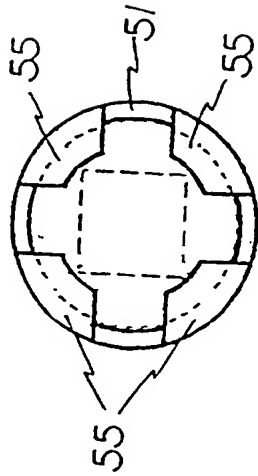


FIG 7

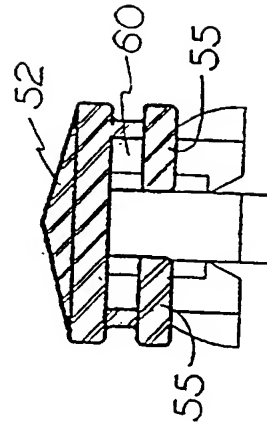


FIG 8

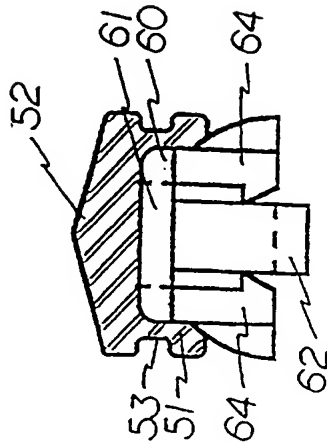


FIG 6

SUBSTITUTE SHEET (RULE 26)

INTERNATIONAL SEARCH REPORT

International Application No

PCT/CA 97/00066

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M5/50

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	CA 2 045 499 A (FENET) 11 July 1990 cited in the application & WO-A-9007949 see abstract, figures 1,2	1,6
A	DE 40 34 673 A (BADER & PARTNER MEDIZINTECHNIK GMBH) 2 April 1992 see column 6, line 47 - column 7, line 60 see figures 1,2	1,6

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

- * "A" document defining the general state of the art which is not considered to be of particular relevance
- * "E" earlier document but published on or after the international filing date
- * "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- * "O" document referring to an oral disclosure, use, exhibition or other means
- * "P" document published prior to the international filing date but later than the priority date claimed

- * "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- * "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- * "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- * "&" document member of the same patent family

Date of the actual completion of the international search

13 May 1997

Date of mailing of the international search report

23.05.97

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax (+31-70) 340-3016

Authorized officer

Sedy, R

INTERNATIONAL SEARCH REPORT

Information on patent family members

In tional Application No

PCT/CA 97/00066

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
CA 2045499 A	11-07-90	FR 2643257 A	24-08-90
		DE 69002322 T	20-01-94
		EP 0453467 A	30-10-91
		ES 2044551 T	01-01-94
		WO 9007949 A	26-07-90
		JP 4502565 T	14-05-92
		OA 9377 A	15-09-92
		US 5257976 A	02-11-93
DE 4034673 A	02-04-92	NONE	

Form PCT/ISA/210 (patent family annex) (July 1992)